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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/038,723 | 01/02/2002 | Bjarne Roenfeldt Nielsen | 5636.210-US | 6089 |

25908 7590 07/01/2004

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

| EXAMINER | |
|---|---|
| RAO, MANJUNATH N | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/038,723 | NIELSEN ET AL. | |
| | Examiner | Art Unit | |
| | Manjunath N. Rao, Ph.D. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *141-240 and 242-253* is/are pending in the application.

4a) Of the above claim(s) *144-240 and 242-253* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *141-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 141-240, 242-253 are currently pending and are present for examination. Claims 141-143 which reads on the elected species are now under consideration. Claims 144-240, 242-253 remain withdrawn from consideration as they are directed to non-elected subject matter.

Applicants' amendments and arguments filed on 4-9-04 have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Sequence Compliance*

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicant fails to provide SEQ ID NO to nucleic acid sequences recited in the specification, for example, see page 42. See particularly 37 CFR 1.821(d).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 141-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 141-143 are drawn to an isolated variant of a parent glucoamylase comprising a mutation of the position 402 in SEQ ID NO:2 or at a corresponding position in a homologous glucoamylase having at least 80% sequence homology with SEQ ID

NO:2. However, it is not clear to the Examiner whether said variant continues to have the glucoamylase activity even after making the above mutation. Amending the claim to recite the function of the variant would overcome this rejection.

Claims 141-143 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 141-143 are directed to variant polypeptides SEQ ID NO:2 or those that have a sequence identity of at least 80%, 90% or 95% with SEQ ID NO:2. Claims 141-143 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:2 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of specific amino acid residues in SEQ ID NO:2 and fragments of SEQ ID NO:2 that have not been disclosed in the specification. No information, beyond the characterization of the structure (i.e., the per cent homology of the sequences and the specific amino acid positions) of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the function of all the polypeptide sequences derived from SEQ ID NO:2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore,

one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Amending the claim to recite the function of the variant such as "wherein said variant continues to have glucoamylase activity" or the like would overcome the above rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 141-142 are rejected under 35 U.S.C. 102(a) as being anticipated by Allen et al. (WO 9803639-A1, 1-29-1998). This rejection is based upon the public availability of a printed publication. Claims 141-142 of the instant application are drawn to a glucoamylase wherein said glucoamylase comprises a mutation (i.e., a substitution, deletion or addition of an amino acid) at specific positions in SEQ ID NO:2 or at a corresponding position in a homologous glucoamylase having at least 80% or 90% homology with SEQ ID NO:2. Allen et al. disclose a variant glucoamylase which has an amino acid sequence identity of more than 90% and wherein the polypeptide is mutated by deletion of first 25 amino acids of SEQ ID NO:2, thereby anticipating claims 141-142 as written.

Examiner is aware that applicants have elected position 402 as the species for examination and said amino acid remains unchanged in the reference cited above. The above rejection is made because Examiner was unable to find a variant glucoamylase with a mutation at position 402 (except for the Double patenting rejection below) during his search and in accordance with the species election requirement, he has randomly selected the next species for examination which now involves the amino acids in position 1-19, 21-25.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 141 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,352,851. This is a double patenting rejection. Examiner is aware that claim 1 of the above patent is directed to a variant of SEQ ID NO:2 or an amino acid sequence that is 60% identical to SEQ ID NO:2 as opposed to claim 141, wherein the claim is directed to a variant of SEQ ID NO:2 or an amino acid sequence that is 80% identical to SEQ ID NO:2. It should be noted that both claims are directed to the respective amino acid sequences in the alternative. Therefore, claim 141 of the instant application and claim 1 of the patent are

identical with respect to the portion of claim directed to the variant of SEQ ID NO:2 and encompassing position 402.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 141-143, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,352,851 which claims a variant glucoamylase wherein the amino acid at position 402 is modified. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 141-143 of the instant application and claims 1-2 of the reference patent are both directed to variants of glucoamylase having an amino acid sequence SEQ ID NO:2 or a sequence that is at least 80%, 90% or 95% identical to SEQ ID NO:2 (SEQ

ID NO:2 of the reference and the instant application are 100% identical) and comprising an alteration at an amino acid corresponding to position 402. The different % homologies of SEQ ID NO:2 claimed in the instant application are encompassed in the % homology (i.e., amino acid sequence 60% identical to SEQ ID NO:2) claimed in the reference patent. The portion of the specification (and the claims) in the reference patent that supports the recited amino acid position on SEQ ID NO:2 and the % homology of SEQ ID NO:2 includes several embodiments (% homology of SEQ ID NO:2 and the amino acid position) that would anticipate the subject matter claimed in claims 141-143. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-2 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 141-143 of the instant application. Alternatively, claims 141-143 cannot be considered patentably distinct over claims 1-2 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-2 of that patent and falls within the scope of claims 141-143 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-2 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., a variant of a parent glucoamylase with SEQ ID NO:2 or a sequence that is at least 80%, 90% or 95% identical to SEQ ID NO:2 comprising amino acid change at position 402. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-2 of the reference patent.

In response to the previous Office action, applicant has submitted that a Terminal Disclaimer will be filed. However, since no such T.D. as been filed as of this day, the above rejection is maintained for reasons of record.

***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao
June 23, 2004